REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of one month of the period for response to the Office Action. Authorization to charge the fee to our deposit account is enclosed.

The Examiner maintained rejection of claims 26 to 30 under 35 USC 103(c) as being unpatentable over Murray (US 6,005,076). Reconsideration is requested having regard to the following remarks.

Claim 26 is directed to a process of preparing a canola protein isolate from canola oil seed meal by a series of process steps. The process steps comprise:

- extracting the canola oil seed meal to cause solubilization of the protein in the canola oil seed meal to form an aqueous protein solution having a pH about 5 to about 6.8,

- separating the aqueous protein solution from residual oil seed meal,

- increasing the protein concentration of the aqueous protein solution while maintaining the ionic strength substantially constant by effecting ultrafiltration of the aqueous protein solution to provide a concentrated protein solution,

- subjecting the concentrated protein solution to diafiltration using 2 to about 20 volumes of diafiltration solution until no significant further quantities of phenolics and colour are present,

- diluting the diafiltered protein solution into chilled water having a temperature below about 15°C to cause the formation of discrete protein micelles in the aqueous phase,

- settling the protein micelles to form an amorphous, sticky, gelatinous, gluten-like protein micellar mass, and

- recovering the protein micellar mass from supernatant, the protein micellar mass having a protein content of at least about 90 wt% (N x 6.25) on a dry weight basis.

The Examiner points out that Murray discloses many of these steps. However, it is noted that claim 26 recites the sequential steps of:

- increasing the protein concentration of the aqueous protein isolate while maintaining the ionic strength substantially constant by use of a selective membrane technique to provide a concentrated protein solution.

- subjecting the concentrated protein solution to diafiltration using about 2 to about 20 volumes of diafiltration solution, until no significant further quantities of phenolics and colour are present in the permeate.

To clarify that the steps are sequential, claim 26 has been amended to recite "the sequential steps of".

While, as the Examiner states, Murray discloses a diafiltration step in col. 7, lines 45 to 50 and concentration by using a retentive ultrafiltration membrane with a molecular weight cut-off of 30,000 in col. 7, lines 10 to 15, these steps do not anticipate or render obvious applicants recited steps. Incidentally, it is noted that the ultrafiltration step described in col. 7, lines 10 to 15 constitutes the step of increasing the protein concentration of diafiltered protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution. The latter step is not a separation step disclosed by Murray, as suggested by the Examiner's analysis.

Applicants claims are directed to procedures for producing a canola protein isolate of improved colour. In the procedure of claim 26, there is a colour

removal step which comprises the diafiltration step effected on the concentrated canola protein solution.

Murray is wholly silent as to any procedure which results in a canola protein isolate of improved colour. To the extent that Murray discloses the steps of diafiltration and concentration by ultrafiltration, in Example 2, the procedure effects first diafiltration and second ultrafiltration. By way of contrast, in claim 26, applicants first effect concentration by ultrafiltration and then colour removal by diafiltration. As recited in claim 26, the diafiltration step is effected using about 5 to 20 volumes of diafiltration medium until no significant quantities of phenolics and visible colour are present in the permeate. The Murray reference is silent as to any particular conditions for diafiltration.

In addition, not only does Murray et al not disclose the steps of concentration of the canola protein solution followed by diafiltration using 2 to 20 volumes of diafiltration solution, the reference also fails to disclose or suggest the use of 5 to 10 volumes of diafiltration solution as specified in claim 28. Claim 29 requires that the extraction step is effected using a salt solution having a pH range of about 5 to 6.8 and that the diafiltration is effected using a diafiltration solution which is an aqueous salt solution having the same concentration and pH as the solution used in the extraction step. While Murray et al discloses that the extraction step may be effected using an aqueous salt solution having a pH in the range of about 5 to about 6.8, to the extent Murray et al discloses diafiltration, there is no disclosure or suggestion to use such solution as the diafiltration medium.

With respect to claim 30, this claim specifies that the diafiltration is effected using a membrane having a molecular weight cut-off in the range of about 3000 to about 50,000 daltons. There is no disclosure in Murray et al of any such membrane for diafiltration.

While the Murray et al reference refers to effecting a diafiltration step, a step carried out at a different stage of operation from that specified in applicants

claims, there is no guidance provided by the reference as to the process conditions to be employed in such operation in the context of obtaining a canola protein isolate of improved colour, as required by applicants claims.

In the Final Action, the Examiner states:

> "Since Murray subject the same plant material to the same isolation and purification process as currently being claimed, the diafiltration process is deemed to remove the colour and phenolics as recited in the amended claims."

As explained above, the applicants do not use the same isolation and purification process in Murray. Applicants effect ultrafiltration to concentrate the aqueous protein solution followed by diafiltration to remove phenolics and colour.

The Examiner further states in the Final Action:

> "Murray is well aware the process of removing colour, as Murray states 'ultrafiltration and similar selective membrane techniques permit low molecular weight species to pass there through while preventing higher molecular weight species from so doing. The low molecular weight species include not only the ionic species of the food grade salt but also low molecular weight materials extracted from the source material, such as carbohydrates, pigments (the same as colour) etc. The molecular weight cut-off of the membrane is usually chosen to ensure retention of substantially all of the proteins in the solution' col. 5, lines 12-26)."

It is true that Murray indicates the ultrafiltration and similar selective membrane techniques permit pigments to pass the membrane. However, this does not mean that Murray effects a specific diafiltration step at a specific stage of the process under specific conditions with the express purpose of removing phenolics and colour.

The Examiner further recites in the Final Action:

> "In addition, although Example 2 itself does not teach the conditions for diafiltration step, Example 2 refers to Example 1,

> wherein Murray teaches 'the high protein liquid extract was diluted 15 fold in tap water", which falls into the range of "2-20 volumes of diafiltration solution' in the amended claims."

The Examiner appears to be confusing the diafiltration step, the ultrafiltration concentration step and the dilution step. The product from the ultrafiltration concentration step in Murray is diluted in cold water. As specified in both Examples 1 and 2, this dilution is effected 15 fold in cold water to effect the formation of canola protein micelles, the differences between the Examples being the temperature of the water.

The dilution step to form the protein micelles is not a diafiltration step, when the concentrates of the solution remains substantially constant, and does not constitute a diafiltration step using 2 to 20 volumes of diafiltration medium, as suggested by the Examiner.

Having regard to the above, it is submitted that claims 26 to 30 are patentable over the applied prior art and hence the rejection of claims 26 to 30 as being unpatentable over Murray, should be withdrawn.

The Examiner again rejected claims 19, 20, 22 to 26, 28 to 36, 38 to 45 and 50 to 52 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656). Reconsideration is requested having regard to the following remarks.

These claims include two independent claims, namely claims 19 and 26. Claims 26 to 30 and their relationship to the Murray reference have been discussed above. As discussed above, the Murray reference is silent as to any suggestion to effect concentration of the aqueous canola protein solution followed by diafiltration under specified conditions in a procedure to obtain a canola protein isolate of improved colour.

Claim 19 specifies a step of washing the canola oil seed meal with an alcohol under specific condition, in this regard, the Examiner admits that:

> "Murray does not teach washing the canola oil seed meal with a alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible colour is recovered, diafiltration solution contains an antioxidant (ascorbic) or any claimed amounts of antioxidant, membrane cut off point."

Certain of these features appear in the subclaims.

The Examiner discusses Jones '656 and its recognition of colour as a problem with canola and relies on this reference for certain teachings, considering that:

> "It would have been prima facie obvious for one ordinary skill at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible colour is recovered, and inactivating myrosinases in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above."

The features to which the Examiner refers are in subsidiary claims to claim 26. The use of antioxidant in the extracting process is recited in claim 35. Washing rapeseed itself with aqueous ethanol is not claimed but rather washing the meal with an alcohol is claimed (claim 36). The inactivation of myrosinases is claimed in claim 50. In any event, the Examiner does not use the Jones '656 reference to make up for the deficiencies of Murray as the primary reference with respect to claim 26.

Other features of the rejected claims not found in either Murray or Jones '656 are:

> - claim 31: The diafiltration membrane of claim 30 has a molecular weight cut-off of about 500 to about 10,000 daltons
>
> - claims 32 to 34: The diafiltration solution contains an antioxidant.
>
> - claims 38 to 45: The supernatant from the deposition of the canola protein isolate is processed to produce a further canola protein isolate.

- claim 51: The canola oil seed meal is air-desolventized at a temperature below about 50°C to remove residual oil extraction solvent.

- claim 52: The canola oil seed meal is desolventized at an elevated temperature below about 100°C to remove residual oil extraction solvent.

Turning now to claims 19 to 25, the feature of claim 19 which distinguishes it from Murray is step (a), namely washing the oil seed meal with an alcohol. Jones '656 discloses contacting defatted seed material from, *inter alia*, rapeseed (canola), with an aqueous-lower alkanol solvent solution under substantially non-oxidizing conditions. The extraction is carried out on oil seed flour to extract contaminants and leave a concentrate. Jones '656 do not prepare a protein isolate.

In contrast, applicants use an alcohol, not an aqueous alkanol solution as in Jones '656, to extract phenolics and/or visible colour from the canola oil seed meal, under specific process conditions as specified in claim 19.

In the Final Rejection, the Examiner states:

"The result-effective adjustment in conventional working parameters, such as determining the concentration of alcohol to wash rapeseed, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan."

As has been pointed out above, the applicants effect a washing with alcohol, not aqueous alcohol, as taught by Jones et al. Applicants procedure involves dispersing the canola oil seed meal in the alcohol at a w/v ratio of about 1:3 to about 1:10, stirring the resulting slurry for about 5 to about 60 minutes at a temperature of about 15° to about 45°C, and separating the washed canola oil seed meal from the slurry. There is nothing in Jones '656 which in any manner suggests these specific conditions for extraction of canola oil seed meal. It is submitted that

applicants process conditions do not represent more optimization and result-effective adjustment in conventional working parameters.

Accordingly, it is submitted that claims 19, 20, 22 to 26, 28 to 36, 38 to 45 and 50 to 52 are patentable over the applied combination prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656), should be withdrawn.

The Examiner again rejected claims 19, 20, 22 to 26, 28 to 36, 38 to 45 and 50 to 54 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,636) and further in view of Jones et al (US 6,146,449). The Examiner has again mis-identified the second Jones et al reference. The correct number is US 6,146,669 ("Jones "669").

This rejection differs from the prior one in adding claims 53 and 54 to the rejection and the Jones '669 reference. The relevance of the Murray and Jones '656 references to the patentability of claims 19 to 36, 38 to 45 and 50 to 52 has been discussed above. Claims 53 and 54 are dependent on claim 26 and are directed to effecting pasteurization of the diafiltered protein solution prior to the diluting step.

Jones '669 is directed to the preparation of a high protein nutrient from oilseed-based material. The Examiner apparently relies on this reference for a teaching that, in a process that involves the incubation of a protein-containing nutrient in a culture medium that contains oilseed-based material, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

The procedure described in Jones '669 for the preparation of an oil seed protein product is wholly different from applicants process of preparing a canola protein isolate. There would appear to be nothing in the Jones '669 reference which would cause a person skilled in the art to modify the process described in the prior art to incorporate the pasteurization step claimed in claims 53 and 54.

Accordingly, it is submitted that claims 19, 20, 22 to 26, 28 to 36, 38 to 45 and 50 to 52 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Murray in view of Jones et al and Jones et al, should be withdrawn.

The Examiner again rejected claims 19, 20, 22 to 26, 28 to 36 and 38 to 54 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,636) and Jones et al (US 6,146,669) and further in view of Diosady (US 6,905,713).

This rejection differs from the prior rejection in including rejection of claims 46 to 49 and the additional reference to Diosady. The relevance of the Murray, Jones '656 and Jones '669 references to the patentability of claims 19 to 36, 38 to 45 and 50 to 54 has been discussed above. Claims 46 to 49 refer to contacting the diafiltered protein solution of claim 26 with a colour-adsorbing agent prior to the diluting step. The colour-adsorbing agent may be polyvinylpyrrolidone (claim 47).

The Diosady et al reference is concerned with the production of high quality canola protein isolates. The Examiner refers to a specific teaching that, in Example 2, col. 23, lines 10 to 15, insoluble PVP is added to treat the solution for one hour and then is separated by filtration. The Examiner considered that, on the basis of that teaching:

> "It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the PVP in Diosady et al, as evidenced by Field, tannic acid content can be absorbed on PVP, thus the dark brown-black pigments could be removed."

Field relates to treating waste water containing phenolic compounds and non-phenolic compounds. Field effects an initial oxidative polymerization of the phenolic compounds followed by an anaerobic purification procedure. Polyvinylpyrrolidone is used to determine the residual toxicity of the waste water following the oxidative polymerization.

In the procedure described in Diosady, in Example 2, canola oil seed meal is extracted with sodium hydroxide solution in the presence of sodium sulphite and the residual meal is separated by centrifugation and the supernatant polished using filter paper. Following addition of NaCl and SDS, the solution is reduced in volume by ultrafiltration and then the concentrated solution is diafiltered. After the diafiltration, the solution is acidified to precipitate what is termed "precipitated protein isolate" (PPI).

The PPI is an isoelectrically precipitated product of the Diosady process, analogous to the protein micellar mass produced in applicants process and in Murray. The PVP treatment step in Diosady is applied to the solution following separation from the PPI. The PVP treatment step in Diosady is not effected prior to separation of the protein isolate but rather subsequently and would be considered to be the equivalent of the treatment of the supernatant from the protein micellar mass produced herein and in the Murray reference.

Accordingly, there is no teaching in Diosady which suggests treatment of the diafiltered concentrated canola protein solution with PVP or other colour-adsorbing agent, prior to dilution to form the protein micelles.

In the Final Action, the Examiner stated:

> "Diosady et al teach the production of high-quality protein isolates from defatted meals (see Title). In the process of isolating protein from canola meal, five grams of insoluble PVP was added to treat the solution for an hour, and then separated by filtration (col 23, lines 10-15). It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the PVP in Diosady et al, as evidenced by Field, tannic acid content can be absorbed on PVP, thus the dark brown-black pigments could be removed."

The Examiner does not explain how the PVP of Diosady is to be used in the present process from the teachings of Diosady et al with respect to such use.

Accordingly, it is submitted that claims 19, 20, 22 to 26, 28 to 36 and 38 to 54 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Murray in view of Jones et al and Jones et al and further in view of Diosady, should be withdrawn.

The Examiner again rejected claims 19, 20, 22 to 26, 28 to 45 and 50 to 54 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656) and Jones et al (US 6,146,669) and further in view of Holbrook (US 6,132,795). Reconsideration is requested having regard to the remarks herein.

This rejection differs from the prior rejection of the claims based on Murray, Jones '656 and Jones '669 in including claim 37 and additionally citing Holbrook. The relevance of the combination of Murray, Jones '656 and Jones '669 to the patentability of claim 19 to 36, 38 to 45 and 50 to 54 has been discussed above and the patentability thereover established. Claim 37 recites that the protein micellar mass of claim 26 is extracted with an aqueous alcoholic solution.

The Holbrook et al reference teaches a vegetable protein composition. The Examiner points to col. 5 for a teaching that the vegetable protein concentrate or isolate is an alcohol extracted or washed material and to cols. 8 and 9 that the protein can be canola protein.

The Examiner conclusion is that:

> "It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract canola protein isolate with aqueous alcoholic solution as Holbrook et al teach that alcohol extraction provides a protein material especially suitable for use in a food material."

Whatever conclusion the Examiner may reach with respect to claim 37, this claims is dependent on claim 26 which has been shown to be patentable over the basic combination of prior art.

Accordingly, it is submitted that claims 19, 20, 22 to 26, 28 to 45 and 50 to 54 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over Murray et al in view of Jones et al and Jones et al and further in view of Diosady, should be withdrawn.

The Examiner again rejected claims 19, 20, 22 to 26 and 28 to 54 under 35 USC 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656) and Jones et al (US 6,146,669) and further in view of Diosady et al (US 6,905,713) and Holbrook et al (US 6,132,795). Reconsideration is requested having regard to the remarks herein.

This rejection differs from the preceding one in including claims 46 to 49 and further reciting the Diosady reference. The combination of Murray and Jones '656 and '669 and further in view of Holbrook with respect to claims 19 to 45 and 50 to 54 has been discussed above. The combination of Murray with Jones '656 and Jones '669 and further in view of Diosady with respect to claims 19 to 36 and 38 to 54 has been discussed above. The respective groups of claims have been demonstrated to be patentable over the respective combinations of prior art.

Accordingly, it is submitted that the rejection of claims 19, 20, 22 to 26 and 28 to 54 under 35 USC 103(a) as being unpatentable over Murray with Jones '656 and Jones '669 and further in view of Diosady and Holbrook, should be withdrawn.

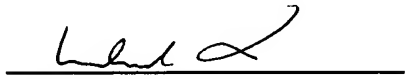
Entry of this Amendment after Final Action is requested in that the application thereby is placed in condition for allowance. In the event the Examiner considers one or more ground of rejection still to apply, the Amendment nevertheless should be entered, in that the claims thereby are placed in better condition for appeal.

Enclosed is a PTO-1449 and a copy of literature references cited therein with respect to prior art not of record herein and cited in a foreign

prosecution. Authorization to charge the prescribed fee to our deposit account is enclosed.

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,



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